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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/505,263

07/29/2005

David B. Mount

1242/50/2 PCT/US

1904

25297

7590

10/03/2007

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EXAMINER

BUNNER, BRIDGET E

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

10/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/505,263

Applicant(s)

MOUNT ET AL.

Examiner

Bridget E. Bunner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-87 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-10, 17-18, drawn to an isolated polypeptide comprising a functional human SLC26A6 polypeptide of SEQ ID NO: 2, 4.

Group 2, claim(s) 1-10, 17-18, and 23-24 drawn to an isolated polypeptide comprising a mouse SLC26A6 polypeptide of SEQ ID NO: 6 or 8.

Group 3, claim(s) 11-16 and 19, drawn to an isolated nucleic acid molecule encoding a human SLC26A6 polypeptide and a system for recombinant expression.

Group 4, claim(s) 11-13, 20-22, and 25, drawn to an isolated nucleic acid molecule encoding a mouse SLC26A6 polypeptide and a system for recombinant expression.

Group 5, claim(s) 26-37, drawn to a method for identifying a modulator of a human SLC26A6 polypeptide of SEQ ID NO: 2, 4 by determining SLC26A6 function.

Group 6, claim(s) 26-37, drawn to a method for identifying a modulator of a mouse SLC26A6 polypeptide of SEQ ID NO: 6, 8 by determining SLC26A6 function.

Group 7, claim(s) 38 and 45, drawn to an anion transporter molecule.

Group 8, claim(s) 39-41 and 46-51, drawn to a method for modulating anion transport activity in a subject.

Group 9, claim(s) 42-43, drawn to a method for identifying an anion exchanger modulator of a mouse SLC26A6 polypeptide of SEQ ID NO: 6, 8 by determining binding.

Group 10, claim(s) 42, 44, drawn to a method for identifying an anion exchanger modulator of a human SLC26A6 polypeptide of SEQ ID NO: 2, 4 by determining binding.

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Group 11, claim(s) 52-54 and 58, drawn to an isolated nucleic acid molecule encoding a mouse SLC26A1 polypeptide of SEQ ID NO: 10 a system for recombinant expression.

Group 12, claim(s) 55-57, drawn to an isolated mouse SLC26A1 polypeptide.

Group 13, claim(s) 59-60, drawn to a method for identifying a modulator of a mouse SLC26A1 polypeptide of SEQ ID NO: 10 by determining SLC26A1 function.

Group 14, claim(s) 61 and 64, drawn to an anion transporter modulator.

Group 15, claim(s) 62-63, drawn to a method for identifying an anion exchanger modulator of a mouse SLC26A1 polypeptide of SEQ ID NO: 10 by determining binding.

Group 16, claim(s) 65-66, drawn to a method for activating a SLC26A1 polypeptide comprising administering a SLC26A1 modulator to a subject.

Group 17, claim(s) 67, drawn to a method for modulating a SLC26A2 polypeptide comprising administering a SLC26A2 modulator to a subject.

Group 18, claim(s) 68-70, drawn to an isolated nucleic acid molecule encoding a porcine SLC26A6 polypeptide.

Group 19, claim(s) 71-72, drawn to an isolated porcine SLC26A6 polypeptide of SEQ ID NO: 91.

Group 20, claim(s) 73-75, drawn to an isolated nucleic acid molecule encoding a *Xenopus laevis* SLC26A6 polypeptide.

Group 21, claim(s) 76-77, drawn to an isolated *Xenopus laevis* SLC26A6 polypeptide of SEQ ID NO: 89.

Group 22, claim(s) 78-80, drawn to an isolated nucleic acid molecule encoding a *Xenopus laevis* SLC26A1 polypeptide.

Group 22, claim(s) 81-82, drawn to an isolated *Xenopus laevis* SLC26A1 polypeptide of SEQ ID NO: 87.

Group 23, claim(s) 83-85, drawn to an isolated *Xenopus laevis* SLC26A4 nucleic acid molecule of SEQ ID NO: 80.

Group 24, claim(s) 83-85, drawn to an isolated *Xenopus laevis* SLC26A4 nucleic acid molecule of SEQ ID NO: 82.

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Group 25, claim(s) 83-85, drawn to an isolated *Xenopus laevis* SLC26A4 nucleic acid molecule of SEQ ID NO: 84.

Group 26, claim(s) 86-87, drawn to an isolated *Xenopus laevis* SLC26A4 polypeptide of SEQ ID NO: 81.

Group 27, claim(s) 86-87, drawn to an isolated *Xenopus laevis* SLC26A4 polypeptide of SEQ ID NO: 83.

Group 28, claim(s) 86-87, drawn to an isolated *Xenopus laevis* SLC26A4 polypeptide of SEQ ID NO: 85.

2. The inventions listed as Groups I-28 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claim 1 broadly encompasses any SLC26A6 polypeptide. Waldegger et al. (Genomics 72: 43-50, 2001) teaches an isolated SLC26A6 polypeptide that is 99.7% identical to SEQ ID NO: 2 of the instant application (see Figure 1 of Waldegger et al.). Thus, the technical feature of claim 1 is not a contribution over the prior art and is not considered a special technical feature.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102,

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103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoiner in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoiner.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory Information

Applicant is advised that the final rules on claims and continuations were published in the Federal Register Tuesday, August 21, 2007. As of November 1, 2007, the claims in each application may not exceed 5 independent claims or 25 total claims absent the applicant assisting the examination process through the filing of an Examination Support Document (ESD). The following is taken from the published rules package:

- **Applicants may present, without an ESD, up to:**
 - **Five (5) independent claims or**
 - **Twenty-five (25) total claims in an application.**

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- **Applicant may present more than 5/25 claims, if applicant files an ESD before the first Office action on the merits (FAOM).**
- **The 5/25 claim threshold does not count withdrawn claims.**
 - **Applicant may provide a suggested restriction requirement (SRR) before first Office action or a restriction requirement.**
- **The 5/25 claim threshold does count all of the claims present in other copending application(s) having a patentably indistinct claim, but not the claims in issued patents.**
 - **Applicant may present up to 15/75 claims via an initial application and 2 continuation or CIP applications prosecuted serially.**

The final rules will become effective November 1, 2007, and will apply to all pending applications as of that date. Applicants are advised to ensure that the elected claims are compliant with the new rules to avoid delay of prosecution. There will be no change to the examiner practice prior to the date the rules become effective. Information on the new rules will be available at:

<http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html>

If Applicant has any questions concerning the new rules, email patentpractice@uspto.gov or call 571-272-7704.

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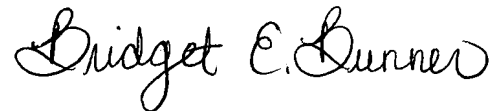
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881.

The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB
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29 September 2007



BRIDGET E. BUNNER
PRIMARY EXAMINER